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(54) GUIDE WIRE FOR CATHETERS AND METHOD OF MANUFACTURING SAME.

(57) A guide wire for a catheter, which is used to guide a catheter into a body cavity, such as a blood vessel, wherein a base material forming this wire consists of a linear elastic alloy, the base material being heat treated so that the flexibility thereof increases progressively from the base thereof toward the tip thereof. At least the tip of this linear base material may be covered with a thermoplastic resin and/or a coiled spring. A method of manufacturing such a catheter guide wire, consisting of the steps of dividing the chip of the base material into a plurality of sections, and heat treating these sections at different temperatures and under different time conditions so that the flexibility of the base material increases progressively from the base thereof toward the tip thereof.

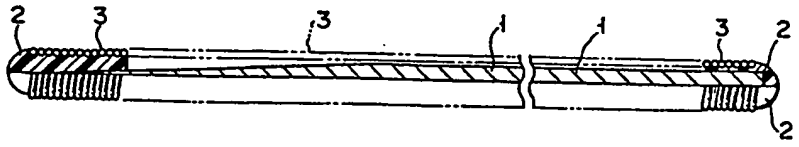

FIG. 3

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SPECIFICATION

Catheter guide wire and manufacturing method thereof

Technical Field

The present invention relates to a catheter guide wire for guiding a clinical or testing catheter to a predetermined portion of a body cavity such as a blood vessel, a digestive tract, and a windpipe and holding it therein, and a method of manufacturing the same.

Prior Art

When a catheter is to be guided to a branching peripheral portion of a blood vessel or the like, first, a guide wire must be guided to a target portion. In this case, since a target portion is generally thin and thus tends to be easily damaged, the distal end portion of the guide wire must be flexible so that it will not damage a blood vessel wall, will follow the shape of the blood vessel well even if the blood vessel is curved, and can be inserted in a complex branching blood vessel. Meanwhile, the proximal end portion of the guide wire must have torque transmitting performance so that a manual operation performed at the proximal end portion is transmitted to the distal end portion. Thus, the proximal end portion of the guide wire must have comparatively high rigidity.

According to a conventional catheter guide wire having the above characteristics, a coil guide wire is

made of a stainless steel wire or a piano wire, or a guide wire is made of a plastic monofilament. In each of these guide wires, its sectional area is decreased from its proximal to distal end portion, and the guide wire forms a main portion having relatively high rigidity and a relatively flexible distal end portion.

However, plastic deformation can easily occur in these conventional guide wires, and some manual operation can kink the guide wires. A kinked portion becomes an obstacle during introduction of a catheter, thus rendering smooth introduction operation of a catheter impossible as well as greatly degrading its torque transmitting performance.

A catheter guide wire free from such kinking deformation uses a very elastic alloy (e.g., Ni-Ti alloy) as a core member (see Japanese Patent Disclosure (Kokai) No. 60-63066).

A guide wire using a very elastic alloy is flexible and can restore its original shape after it is deformed to a considerable degree (strain of about 8%). Therefore, such a guide wire cannot be easily broken during operation and will not easily attain a bending tendency. However, such guide wire has a high elasticity at its distal end portion and is thus infavorable in terms of flexibility. Then the diameter of its proximal end portion is 0.5 mm or less, the rigidity is insufficient and the torque transmitting performance is poor.

Disclosure of the Invention

The present invention has been made in view of the above situation and has as its object to provide a catheter guide wire wherein its distal end portion is very flexible, buckling deformation is difficult to occur, and its proximal end portion is very rigid, thus having a good torque transmitting performance to the distal end portion, and a method of manufacturing the same.

In order to solve the above problems, according to

the present invention, a wire member made of an elastic alloy, and preferably a very elastic alloy, is used as a core member of a catheter guide wire and subjected to a heat treatment by changing the treatment conditions along its longitudinal direction, so that the rigidity at its proximal end portion becomes comparatively high, the flexibility at its distal end portion is increased, and kinking deformation will not easily occur in its distal end portion.

More specifically, according to the present invention, there is provided a catheter guide wire having leading and trailing end sides, characterized in that the guide wire comprises a wire member made of an elastic alloy member, at least the leading end side thereof has an outer diameter equal to or smaller than a minimum inner diameter of a catheter, and the wire member is subjected to a heat treatment so that its flexibility is sequentially increased from a proximal to distal end portion of the leading end side thereof.

Note that the catheter guide wire can be fabricated by using as a core member a wire member made of an elastic alloy member subjected to the heat treatment described above and forming a cover layer of a thermoplastic resin on the core member.

The core member preferably uses a very elastic alloy such as an Ni-Ti alloy, a Cu-Zn-Aℓ alloy, a Cu-Aℓ-Ni alloy, and an Fe-Mn alloy. The core member is preferably tapered such that a diameter at its distal end portion is smaller than that at its proximal end portion. A contrast medium such as a tungsten powder can be added to the thermoplastic resin layer.

A flexible coil spring having an outer diameter equal to or smaller than a minimum inner diameter of the catheter can be mounted to surround at least the distal end portion of the wire member.

In this case, the coil spring is preferably made of a material having a high X-ray impermeability in order

to allow an X-ray photographing to be easily confirmed. Therefore, the presence of the coil spring is advantageous in giving a sufficient thickness in an X-ray image without badly affecting the flexibility of the guide wire.

As a result, the coil spring is made of a material selected from a group consisting of stainless steel, platinum, a platinum alloy and a palladium alloy, and preferably has a thickness of 0.01 to 0.15 mm, more preferably 0.05 to 0.1 mm.

Furthermore, according to the present invention, there is provided a method of manufacturing a catheter guide wire fabricated by using an elastic alloy wire as a base material, characterized in that a leading end side of the base material is divided into a plurality of areas, and a heat treatment is performed by changing the temperatures and time in units of the areas so that the flexibility of the base material is sequentially increased from the proximal to distal end portion of the leading end side.

In a conventional catheter guide wire, a diameter at a proximal end portion of a wire member made of an elastic alloy or a very elastic alloy is merely increased, and a diameter at its distal end portion is relatively decreased, thereby making the proximal end portion rigid and the distal end portion flexible. Unlike such a conventional catheter guide wire, according to the present invention, a wire member is subjected to a heat treatment by sequentially changing the confunction along its longitudinal direction. As a result, the physical characteristics of the wire member can be set in an ideal state as a catheter guide wire.

Brief Description of the Drawings

Fig. 1 is a sectional view of a catheter guide wire according to an embodiment of the present invention;

Fig. 2 is a graph of strain-stress curves of the core member of the guide wire according to the

embodiment of the present invention; and

Figs. 3 and 4 respectively represent a sectional view of a catheter guide wire on which a coil spring is mounted according to another embodiment of the present invention.

Best Mode for carrying out the Invention

Preferred embodiments of the present invention will be described with reference to the accompanying drawings.

Fig. 1 is a sectional view of a catheter guide wire taken along the longitudinal direction according to an embodiment of the present invention. Referring to Fig. 1, reference numeral 1 denotes a core member; and 2, a thermoplastic resin layer entirely covering core member 1.

Core member 1 is a wire member made of an elastic alloy wire such as a piano wire, and preferably a very elastic alloy such as an Ni-Ti alloy. Core member 1 can have a uniform diameter of 0.2 to 0.4 mm, or can be tapered toward its distal end such that the diameter at its proximal end portion is 0.2 to 0.4 mm and the diameter at its distal end portion is 0.01 to 0.1 mm. In this specification, a very elastic alloy is defined as an alloy whose recoverable elastic strain is as large as several % to more than ten % and whose stress level does not exceed a predetermined value even if the strain is increased. The very elastic alloy generally comprises an Ni-Ti, Cu-Zn-Aℓ, Cu-Aℓ-Ni, or Fe-Mn alloy. If an Ni-Ti alloy is employed, it preferably contains 49 to 58 atm% of Ni and a balance of Ti, and more preferably 49 to 51 atm% of Ni and a balance of Ti. If a Cu-Zn-Aℓ alloy is employed, it preferably contains 38.5 to 41.5 wt% of Zn, 1 to 10 wt% of ADP, and a balance of Cu. If a Cu-Aℓ-Ni alloy is employed, it preferably contains 14 to 14.5 wt% of Aℓ, 3 to 4.5 wt% of Ni, and a balance of Cu. If an Fe-Mn alloy is employed, it preferably contains 28 to 32 wt% of Mn, 6 wt% of Si, and a balance

of Fe. A heat treatment is performed by changing the treatment conditions. As a result, the guide wire can have the following physical characteristics in its areas (1) to (III) as shown in Fig. 1.

(1) Proximal end portion (I)

When the guide wire is guided from, e.g., a straight great blood vessel (e.g., a descending aorta) to an arteriole (e.g., a coronary artery), proximal end a comparatively small number of bent portions. Proximal and portion (I) has a comparatively high rigidity and is difficult to deform. Therefore, forward/backward movement and rotation externally applied to the catheter can be easily transmitted to the distal end portion (II - III) through a blood vessel retaining an introducer (not shown).

(2) Intermediate portion (II)

Intermediate portion (II) has an elasticity so that it can easily follow a blood vessel curve of a comparatively large curve and can return to its initial shape when deformation caused by the curve is removed. Although it is flexible, intermediate portion (II) hardly attains a bending tendency and is difficult to break.

(3) Distal end portion (III)

When distal end portion (III) is inserted in a small, curved blood vessel, it can easily follow the blood vessel shape due to it's flexibility, and thus will not damage the blood vessel wall. When a blood vessel has phatologic factor such as arteriosclerosis, the flexibility of distal end portion (III) is important.

Thermoplastic resin layer 2 is provided as needed in order to protect the inner surface of the blood vessel, to prevent formation of thrombus on an outer surface of the guide wire during operation of the guide wire, and not to form a difference in outer diameter between the proxital end portion and the distal end

portion. For example, saturated aliphatic polyether urethane is used to form layer 2. A contrast medium can be mixed in the thermoplastic resin in advance in order to increase the contrast of the guide wire through X-ray photographing. For example, 40 to 600 parts by weight (with respect to 100 parts by weight of thermoplastic resin) of a tungsten powder can be mixed as the contrast medium. Note that saturated aliphatic polyether polyurethane is favorable for compounding of tungsten.

Fig. 2 shows the physical characteristics (strain-stress curve) at the respective portions of the core member of the present invention after a heat treatment. A heat treatment can be performed in an atmosphere of an inert gas (Ar or He), vacuum (× 10-2 Torr or less) or outer atmosphere. Although a heat treatment can be performed in an outer atmosphere, it is preferably performed in a vacuum in view of embrittlement of the material, and more preferably in an inert gas. The values in Fig. 2 are obtained by cutting the core member sample into 70-mm long pieces starting from its distal end and subjecting the respective samples to a tension test.

Core member: Ni-Ti alloy wire (diameter: 0.4 mm)
(49 atm% of Ni and a balance of Ti)

Heat treatment conditions:

Area of Guide Wire	Heat Treatment Conditions	Tension Test Sample No.
Distal end portion (III)	About 2 hrs. at 400 to 500°C and about 24 hrs. at 200°C (in outer atmosphere)	(1)(2)
Intermediate portion (II)	About 2 hrs. at 400 to 500°C (in outer atmosphere)	(3)(4)(5)
Proximal end portion (I)	No heat treatment after cold rolling	(6)

The physical characteristics at the respective portions of core member 1 are not limited to those shown in Fig. 2 and can be arbitrarily adjusted and selected in accordance with specific applications.

Fig. 3 is a partial sectional view of a catheter guide wire according to another embodiment of the present invention. Thermoplastic resin layer 2 is formed on the entire surface of core member 1 in the same manner as in Fig. 1, and coil spring 3 having a thickness of 0.08 mm is mounted on an outer surface of resin layer 2 excluding its leading and trailing end faces. Note that coil spring 3 may be provided at only the distal end portion of the guide wire. The outer diameter of the guide wire may be conveniently selected to conform with the inner diameter of a blood vessel to be inserted. Generally, however, the outer diameter of the guide wire may be selected within a range of from 0.2 to 2.0 mm.

When coil spring 3 is applied on resin layer 2 in this manner, the physical characteristics of the guide wire are as flexible at its distal end portion as shown in Fig. 1 and highly resistive to buckling deformation due to the high flexibility of the coil spring 3, relatively high in rigidity at its proximal end portion and excellent in X-ray photographing.

Coil spring 3 can be provided to directly surround core member 1 without intervening thermoplastic resin layer 2.

Fig. 4 shows an example of such a structure of the guide wire, wherein the coil spring 3 is directly wound around the outer wall of core member 1, with its distal and proximal end portions being fixed to core member 1 through a soldering material 4 made for example of Sn-Ag (96:4) alloy.

As described above, according to the catheter guide wire of the present invention, a wire member made of an elastic alloy is used as a core member and subjected to a heat treatment by sequentially changing the treatment conditions along its longitudinal direction. As a result, the proximal end portion of the guide wire has predetermined rigidity required in accordance with its

application, and its distal end portion has predetermined flexibility.

Industrial Application

The guide wire as proposed by this invention is useful for guiding a clinical or testing catheter to a predetermined portion of a body cavity such as blood vessel, a digestive tract and a windpipe, and holding it therein for a period of time.

Claims:

1. A catheter guide wire having leading and trailing end sides, wherein said guide wire comprises a wire member made of an elastic alloy member, at least said distal end side thereof has an outer diameter equal to or smaller than a minimum inner diameter of a catheter, and said wire member is subjected to a heat treatment so that flexibility thereof is sequentially increased from a proximal end portion to a distal end portion of said leading end side.

2. A guide wire according to claim 1, characterized in that said wire member made of an elastic alloy member is tapered at least at said distal end portion.

3. A guide wire according to claim 1, characterized in that said elastic alloy member comprises a very elastic alloy.

4. A guide wire according to claim 3, characterized in that said very elastic alloy is an alloy selected from the group consisting of Ni-Ti, Cu-Zn-Al, Cu-Al-Ni, and Fe-Mn alloys.

5. A catheter guide wire comprising a core member and a thermoplastic resin layer, said core member comprising an elastic alloy wire and being subjected to a heat treatment such that the flexibility thereof is sequentially increased from its proximal end portion to its distal end portion, said thermoplastic resin layer covering said core member.

6. A guide wire according to claim 5, characterized in that said wire member comprising an elastic alloy member is tapered at least at a distal end portion thereof.

7. A guide wire according to claim 5, characterized in that said elastic alloy member consists of a very elastic alloy.

8. A guide wire according to claim 5, characterized in that said very elastic alloy is an alloy

selected from the group consisting of Ni-Ti, Cu-Zn-Aℓ, Cu-Aℓ-Ni, and Fe-Mn alloys.

9. A guide wire according to claim 5, characterized in that a flexible coil spring is mounted on an outer surface of at least a distal end portion of said thermoplastic resin layer.

10. A guide wire according to claim 9, characterized in that said coil spring is made of a material selected from the group consisting of stainless steel, platinum, a platinum alloy and a palladium alloy.

11. A catheter guide wire having leading and trailing end sides, wherein said guide wire comprises a wire member extending from said trailing end side to said leading end side and made of an elastic alloy member, said wire member being subjected to a heat treatment so that its flexibility is sequentially increased from a proximal to distal end portion of said leading end side, and a flexible coil spring having an outer diameter equal to or smaller than a minimum inner diameter of said catheter and mounted to surround at least said distal end portion of said wire member.

12. A guide wire according to claim 11, characterized in that said wire member made of an elastic alloy member is tapered at least at said distal end portion.

13. A guide wire according to claim 11, characterized in that said elastic alloy member consists of a very elastic alloy.

14. A guide wire according to claim 13, characterized in that said very elastic alloy is an alloy selected from the group consisting of Ni-Ti, Cu-Zn-Aℓ, Cu-Aℓ-Ni, and Fe-Mn alloys.

15. A guide wire according to claim 11, characterized in that said coil spring is made of a member selected from the group consisting of stainless steel, platinum, a platinum alloy and a palladium alloy.

16. A method of manufacturing a catheter guide

wire fabricated by using an elastic alloy wire as a base material, wherein a leading end side of said base material is divided into a plurality of areas, and subjected to a heat treatment by changing the heat treatment temperature and time conditions in units of the areas so that the flexibility of said base material is sequentially increased from a proximal end portion to a distal end portion of said leading end side.

17. A method according to claim 16, characterized in that said base material is divided into proximal end, intermediate, and distal end portions, only said intermediate and distal end portions are subjected to a primary heat treatment under given conditions, and thereafter only the distal end portion is subjected to a secondary heat treatment.

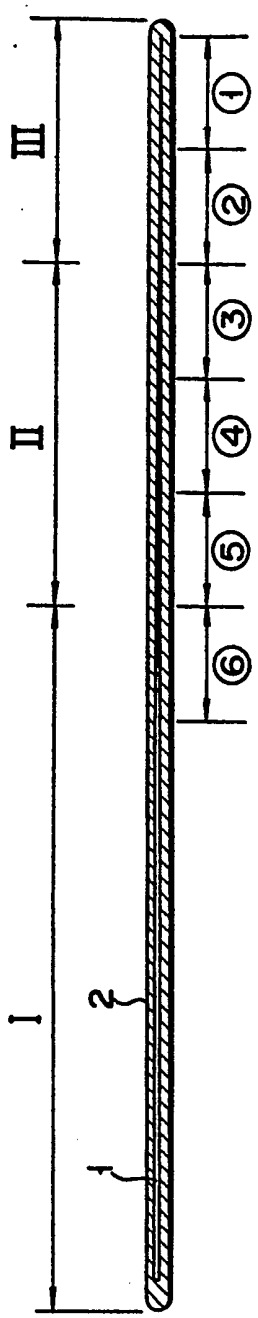

FIG. 1

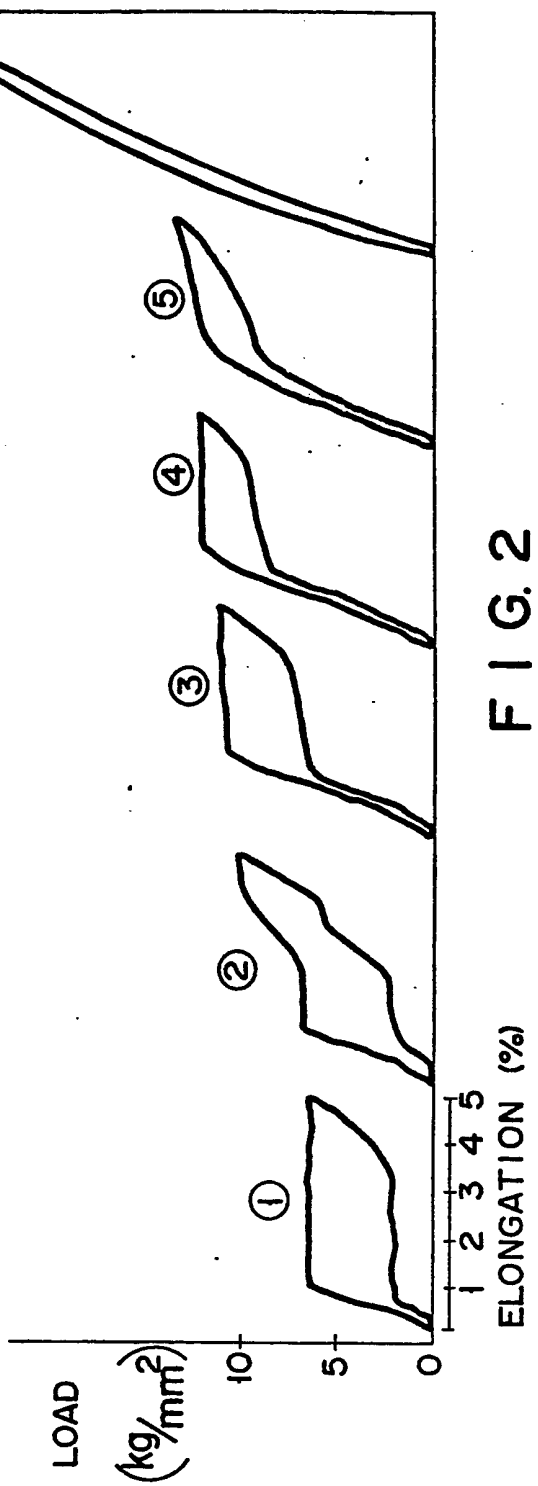

FIG. 2

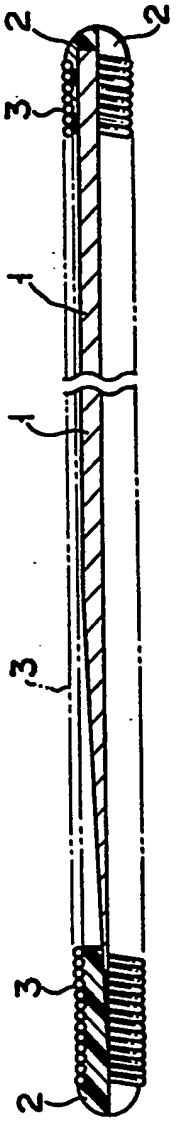

FIG. 3

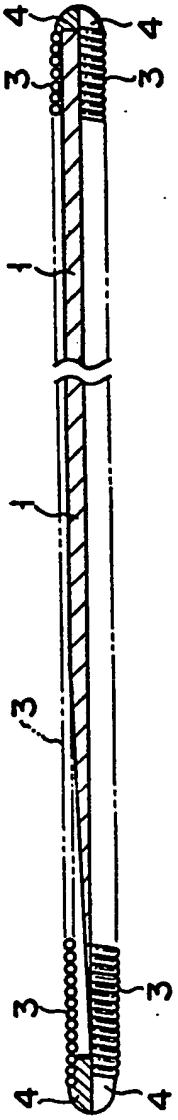

FIG. 4

INTERNATIONAL SEARCH REPORT

International Application No PCT/JP87/01031

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl[4] A61M25/00

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
IPC	A61M23/00, 25/00

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [5]

Jitsuyo Shinan Koho 1955 - 1988
Kokai Jitsuyo Shinan Koho 1971 - 1988

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	JP, A, 60-63066 (Fuji Terumo Kabushiki Kaisha) 11 April 1985 (11. 04. 85) Page 4, left column, 17th line to 11th line from the bottom & EP, A1, 141006	1-17
Y	JP, U, 59-48643 (Terumo Corporation) 31 March 1984 (31. 03. 84) Pages 1 to 2 (Family: none)	9-15

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
March 10, 1988 (10. 03. 88)	March 28, 1988 (28. 03. 88)
International Searching Authority [1]	**Signature of Authorized Officer [20]**
Japanese Patent Office	